SmartPA Criteria Proposal

Drug/Drug Class:	Vijoice Clinical Edit
First Implementation Date:	TBD
Proposed Date:	September 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Vijoice® (alpelisib).

Why Issue Selected: Vijoice® (alpelisib) was FDA-approved on April 5, 2022, for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of *PIK3CA*-Related Overgrowth Spectrum (PROS) who require systemic therapy. PROS is a spectrum of rare disorders involving variants in the *PIK3CA* gene causing overgrowth in various parts of the body. These variants result in an abnormally active phosphatidylinositol-3-kinase (PI3K) enzyme, causing affected cells to grow and divide more than they should. The pathogenic variants in PROS are mosaic and are only present in certain body cells that affect certain areas. Manifestations include abnormal bone, soft tissue, and blood vessel growth in these affected areas. PROS has an estimated prevalence of 14 people per million. Treatment of PROS includes symptom management and treatment of complications such as bleeding, clotting, pain, and functional impairment. Vijoice is the first FDA-approved medication for PROS and acts by inhibiting the PI3K enzyme resulting in decreased tissue overgrowth. Alpelisib was previously approved by the FDA in 2019 for the treatment of cancer and is marketed as Piqray® for the cancer indication.

Due to the high cost, possible adverse events, and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Vijoice.

Program-Specific Information:

Drug	Cost per pack (WAC)	Cost per year (WAC)
VIJOICE 50 MG BLISTER PACK	$32,500.00	$422,500.00
VIJOICE 125 MG BLISTER PACK		
VIJOICE 250 MG BLISTER PACK		

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Vijoice® (alpelisib)

- Age range: All appropriate MO HealthNet participants aged 2 years and older

Approval Criteria

Initial Therapy:
- Prescribed by or in consultation with an appropriate specialist in the treated disease state **AND**
- Participant is aged ≥ 2 years **AND**
- Documented diagnosis of PROS as verified by:
  - Genetic testing **OR**
  - National Institutes of Health (NIH) Workshop Diagnostic Guidelines **AND**
- Documentation of at least one target lesion identified on imaging with baseline measurement of target lesion volume **AND**
- Participants aged ≥ 18 years: therapeutic reason why Piqray 250 mg daily dose pack cannot be utilized
- Initial approval for 6 months

Continuation of Therapy:
- Documentation of benefit of therapy by one of the following from baseline:
  - ≥ 20% reduction in measurement of target lesion volume
  - Reduction in sum of lesion volume
  - Clinically meaningful improvement in signs and symptoms of disease (i.e., vascular malformation, functional improvement, limb asymmetry, pain)
- Continued approval for 1 year

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

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- NIH: U.S National Library of Medicine. Study Assessing the Efficacy, Safety and PK of Alpelisib (BYL719) in Pediatric and Adult Patients With *PIK3CA*-related Overgrowth Spectrum. Study Assessing the Efficacy, Safety and PK of Alpelisib (BYL719) in Pediatric and Adult Patients With *PIK3CA*-related Overgrowth Spectrum - Full Text View - ClinicalTrials.gov. Accessed May 11, 2022.
- NIH: U.S National Library of Medicine. Study Assessing Long-term Safety and Efficacy of Alpelisib in Patients With *PIK3CA*-Related Overgrowth Spectrum (PROS) Who Previously Participated in Study CBYL719F12002 (EPIK-P1) (EPIK-P3). Study Assessing Long-term Safety and Efficacy of Alpelisib in Patients With *PIK3CA*-Related Overgrowth Spectrum (PROS) Who Previously Participated in Study CBYL719F12002 (EPIK-P1) - Full Text View - ClinicalTrials.gov. Accessed May 11, 2022.